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No. 02-396

# In the Supreme Court of the United States

DEY, L.P. AND DEY, INC.,

*Petitioners,*

v.

ABBOTT LABORATORIES AND
MITSUBISHI-TOKYO PHARMACEUTICALS, INC.
(FORMERLY KNOWN AS TOKYO TANABE CO., LTD.),

*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## BRIEF FOR RESPONDENTS IN OPPOSITION

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## QUESTION PRESENTED

1. Given the particular product and process at issue here, did the patent's description of how to "make and use" the claimed invention expressly surrender and disclaim all of the individual elements of all of the raw materials and precursor compounds described at each intermediate stage of the production process, such that the patent-holder is estopped from relying upon the doctrine of equivalents to show that a product that may have an element in common with one of those raw materials or intermediate compounds infringes the patented invention?

2. Should this case be remanded for further consideration in light of this Court's recent decision in *Festo Corp.* v. *Shoketsu Kinzoku Kabushiki Co.*, 122 S. Ct. 1831 (2002), given that the *Festo* case does not conflict in any way with the Federal Circuit's decision in this case?

3. Is the decision below in conflict with an earlier decision of the Federal Circuit in holding that statements made during the prosecution of the '301 patent may not constitute prosecution history estoppel with respect to the '839 patent, which was submitted to the Patent and Trademark Office as an entirely separate patent application?

## RULE 29.6 STATEMENT

Pursuant to Rule 29.6, Respondents inform the Court that Respondent Mitsubishi-Tokyo Pharmaceuticals, Inc.—formerly known as Tokyo Tanabe Co., Ltd.—merged with Welfide Corporation and changed its name to Mitsubishi Pharma Corporation ("MPC") on October 1, 2001. MPC is a publicly traded company whose shares are traded on the Tokyo Stock Exchange. More than 10% of MPC's shares are owned by Mitsubishi Chemical Corporation, the shares of which are also traded on the Tokyo Stock Exchange.

Respondent Abbott Laboratories has no parent corporation, and no publicly held company owns 10% or more of Abbott Laboratories' stock.

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## STATEMENT OF THE CASE

At issue in this case are two unrelated patents – U.S. Patent Nos. 4,397,839 (the '839 patent) and 4,338,301 (the '301 patent) – both of which concern compositions used for the treatment of neonatal respiratory distress syndrome. The composition claimed in the '301 patent was discovered and patented by three Japanese scientists in the 1970s. It claims a "surface active material" obtained from mammalian lungs and enhanced with particular additives. One of the '301 inventors, Dr. Yuji Tanaka, later discovered that compositions like those in the '301 patent could be improved by having higher levels of free fatty acid. Dr. Tanaka's subsequent invention was claimed in the '839 patent application and was presented to the Patent and Trademark Office as a patentably distinct invention and not as a continuation of the '301 patent. Both the '301 and '839 patents were assigned to Tokyo Tanabe Co., Ltd. (now known as Mitsubishi Pharma Corporation) and were licensed to Abbott Laboratories.

Abbott Laboratories and Tokyo Tanabe Co., Ltd. (collectively "plaintiffs" or "plaintiff-respondents") later filed suit and sought a preliminary injunction against Dey, L.P. and Dey, Inc. (collectively "Dey") alleging that a surfactant product distributed and marketed by Dey infringed both patents. Following an evidentiary hearing, the district court denied the motion for a preliminary injunction. Pet. App. 30a-38a. Specifically, the court held that Dey's product infringed each element of Claim 1 of the '839 patent literally, except for the phospholipid element; the claims in the '839 patent specified a phospholipid level of between 68.6% and 90.7%, whereas the Dey product had more than 90.7% phospholipid. *Id.* at 32a-

33a.[1] As for that element, the court found that the phospholipid levels in Dey's product performed the same function, in the same way, and to achieve the same result as the phospholipid levels specified in the '839 patent—a conclusion that would ordinarily suggest a finding of infringement under the doctrine of equivalents. *Id.* at 34a. Nevertheless, the district court held that plaintiffs were estopped from asserting the doctrine of equivalents with respect to the phospholipid element. The court's ruling was based principally on its view that because the '839 patent was an improvement over the '301 patent and contained specific numerical ranges for each component, the claims in the '839 patent are entitled to only a narrow range of equivalents. *Id.* at 35a-36a. The court's ruling was also based on the view that a "hypothetical claim" that actually contained a range of phospholipid up to the level in Dey's composition would not have been allowed over the prior art '301 patent. *Id.* at 36a-38a.

Dey then filed a motion for summary judgment of noninfringement. The district court granted the motion. Pet. App. 23a. The district court held that plaintiffs were estopped from relying upon the doctrine of equivalents because "a competitor would reasonably believe, based on the specification and claims of the '839 patent, and the prosecution history of the unrelated '301 patent, that the patentee relinquished the right to exclude any surface active material containing, among other things, more than 90.7% phospholipid." *Id.* at 27a. In the district court's view, the prosecution history of the '301 patent was significant because, in the course of prosecuting that patent, the applicant had argued that "only a surface-active

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[1] Abbott's tests of Dey's product found that one sample contained 91.8% phospholipid while another sample contained 94.5% phospholipid. Pet. App. 7a.

material having the chemical composition claimed [by the '301 patent]" would be effective. *Forest Laboratories, Inc.* v. *Abbott Laboratories*, 239 F.3d 1305, 1314 (Fed. Cir. 2001). As for the reference to the contents of the '839 patent itself, the district court explained that the specification disclosed that Dr. Tanaka had begun his research by modifying the compound claimed in the '301 patent. According to the court, that reference and history made clear that the numerical percentage ranges in the '839 patent's claims were "significant" and that the changes Dr. Tanaka made to the percentage composition of the '301 patent "were similarly significant." Pet. App. 27a-28a.[2] On that basis, the court concluded that plaintiffs should not be permitted to use the doctrine of equivalents to claim infringement by a composition containing a phospholipid element outside the numerical ranges specified in the claims of the '839 patent.

On appeal, the Federal Circuit rejected the district court's reasoning and held that plaintiffs were not barred by prosecution history estoppel from relying upon the doctrine of equivalents with respect to the phospholipid element. The Federal Circuit took issue with the district court's reliance on the prosecution history of the '301 patent and concluded—based on the particular circumstances of this case—that "the relationship, if any, between the '839 and '301 patents is insufficient to render particular arguments made during prosecution of the '301 patent equally applicable to the claims of the '839 patent." Pet. App. 13a (citations omitted); see *id.* at 13a-15a. The court also rejected the district court's

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[2] The district court did not cite Example 3 of the '839 patent, nor did it hold that any portion of that patent's specification disclosed and expressly disclaimed an alternative formulation with greater than 90.7% phospholipid.

hypothetical claim/prior art analysis, found that the plaintiffs' expert testimony and reliance on the doctrine of equivalents did not completely vitiate the phospholipid element in the '839 patent, and concluded that the patent's use of specific numeric ranges for the various components did not foreclose the use of the doctrine of equivalents. Having vacated the district court's award of summary judgment to Dey, the Federal Circuit remanded the case for further proceedings.

Dey filed a petition for rehearing and suggestion for rehearing en banc, arguing *inter alia* that the panel's opinion was inconsistent with the Federal Circuit's recent en banc opinion in *Johnson & Johnston Assocs., Inc.* v. *R.E. Service Co.*, 285 F.3d 1046 (2002), as well as with that court's previous decision regarding these particular patents in *Forest Laboratories, Inc.* v. *Abbott Laboratories*, 239 F.3d 1305 (2001). The Federal Circuit denied the rehearing petition and declined to take the case en banc.[3]

Dey now seeks this Court's review on similar grounds, submitting a petition that depends in significant part on a factual proposition never adopted by either the district court or the Federal Circuit. Most of the arguments raised in the petition are based on the factual allegation that a compound with a phospholipid level greater than 90.7% was disclosed and "expressly disclaimed" in the specification of the '839 patent. *E.g.*, Pet. 2. Based on that allegation, Dey argues that the

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[3] Dey's petition for certiorari alternatively seeks a remand for further consideration in light of *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002). When *Festo* was handed down, however, Dey did not see fit to bring that case to the Federal Circuit's attention under Federal Rule of Appellate Procedure 28(j), even though the rehearing petition in this case had not yet been decided.

Federal Circuit's ruling effectively allows a patent holder to reclaim "expressly disclaimed" subject matter using the doctrine of equivalents, in supposed conflict with various decisions of both that court and this one. This "express disclaim[er]," Dey argues, may be found in Example 3 of the '839 patent, which describes the *process* of making the patented chemical composition. Dey contends that because one of the intermediate steps in the process involved a preliminary compound containing 92.8% phospholipid, the inventor thereby "disclosed and expressly disclaimed" a composition with more than 90.7% phospholipid as an alternative to the patented invention. Pet. 15. Accordingly, Dey argues that plaintiffs should not be able to rely upon the doctrine of equivalents with respect to the phospholipid element.

Neither the district court nor the Federal Circuit has accepted Dey's factual contention that the '839 patent "expressly disclaims[s]" an alternative composition with a phosopholipid level of more than 90.7%. Although the district court held that plaintiffs could not rely upon the doctrine of equivalents, it based that ruling on limited factors—namely, the prosecution history of the '301 patent, and the fact that the '839 patent was an improvement patent that specified a particular percentage range for each of the components in the composition. Neither the district court—nor the Federal Circuit in rejecting its conclusions—considered this to be a case where subject matter was "expressly disclaimed" in the specification of the patent itself. And neither court even mentioned Example 3 of the '839 patent, in which Dey now locates the alleged "express disclaime[r]" that is so critical to its current position.

## REASONS FOR DENYING THE PETITION

Dey's primary argument in favor of certiorari—namely, that the decision below conflicts with several decisions of the

Federal Circuit and this Court—is based on a factual contention never adopted by either of the courts below. Dey repeatedly contends that the '839 patent "expressly disclaimed" any compound with a phospholipid level of more than 90.7%. Pet. 2, 15, 16. At this stage in the proceedings, however, neither the district court nor the Federal Circuit has accepted that factual characterization. Moreover, as set out below, plaintiffs strenuously dispute Dey's position that the patent "expressly disclaim[s]" phospholipid levels over 90.7%. Given the continuing dispute over this critical factual issue, this case does not truly pose the questions suggested by the petition, nor would it provide a good vehicle for resolving any issue relating to the use of the doctrine of equivalents in cases of express disclaimer.

Moreover, even if Dey's factual supposition were correct, there is no statement in any of the opinions below that could possibly create any conflict of precedent on the issue of whether the doctrine of equivalents is available in cases where a patent expressly disclaims some alternative to the claimed invention. The Federal Circuit's opinion does not mention or discuss Dey's argument that the '839 patent "expressly disclaimed" a compound with a certain phospholipid range, almost certainly because the argument was suggested at most as a sidelight to Dey's principal appellate argument and was obviously meritless, given the circumstances of this case. Regardless of the reason, however, the absence of any discussion on this subject in the decision below (or in the district court's opinions) means that the case will not stand as precedent for the proposition that the doctrine of equivalents is available for subject matter that is expressly disclaimed.

Dey has also failed to demonstrate a need for this Court's intervention in the Federal Circuit's interpretation of these

particular patents. The alleged conflict between the decision below and the decision in *Forest Laboratories, Inc.* v. *Abbott Laboratories*, 239 F.3d 1305 (Fed. Cir. 2001), is illusory. In fact, the two decisions are readily reconcilable—and obviously were reconciled in the view of the Federal Circuit, which declined to grant rehearing or rehearing en banc even after Dey brought the alleged conflict to its attention. In any case, even if the two opinions did conflict, the issue of the relationship between these two particular patents is not a matter appropriate for a grant of certiorari.

## I. The Petition Depends Upon A Factual Supposition Never Adopted By The Courts Below And Strenuously Disputed By Plaintiffs.

Most of the arguments offered in Dey's petition rest on the unproven factual supposition that the '839 patent expressly discloses and disclaims a phospholipid range greater than 90.7%. It is that characterization of the patent that creates the supposed conflict between the decision below and previous decisions of the Federal Circuit (Pet. 15, 16, 18), as well as the supposed conflict with decisions of this Court (Pet. 19, 22). Further, this factual supposition also forms the basis of Dey's argument that the decision below will have some negative effect on patent law generally. Pet. 24. This basic factual predicate to Dey's principal arguments remains highly disputed and has never been adopted or commented upon by the courts below. Under the circumstances, this case is singularly unworthy of certiorari.

### A. The '839 Patent Did Not "Expressly Disclaim[]" Compositions With Higher Phospholipid Levels.

Dey's argument that the '839 patent "expressly disclaim[s]" compositions with higher levels of phospholipid is based upon

Example 3 of the '839 patent – a portion of the patent never cited or mentioned in any of the opinions below. See Pet. 15 (citing Example 3); *id.* at 18 (discussing Example 3 as the location of the "express disclaim[er]"); *id.* at 22 (same effect). Given the context of Example 3 and the nature of the particular compounds at issue, however, it is clear that the patent's Example 3 does not "expressly disclaim[]" anything.

The portion of Example 3 on which Dey relies so heavily clearly refers to a precursor residue containing 92.8% phospholipid that was derived at an intermediate stage in the production process, *not* to an alternative formulation that could substitute for the claimed invention. U.S. Patent No. 4,397,839 col. 13, ll. 15-35 (C.A. J.A. A1113, A1124). In Example 3, minced cattle lungs were combined with saline and filtered to obtain an extract. *Id.* at cols. 11-13 (C.A. J.A. A1123-A1124). The extract was then centrifuged, combined with other materials, and put through a number of further processes to obtain a solid residue, which happened to have a phospholipid content of 92.8%. *Id.* at col. 13, ll. 15-28. Three ingredients (one phospholipid and two neutral lipids) were then added to that solid residue, and the resulting mixture was suspended in distilled water and lyophilized. *Id.* at ll. 29-35. The final product had the chemical composition claimed in the '839 patent. *Id.* There is no evidence that the three added ingredients were intended to decrease the percentage content of phospholipid or to dedicate the higher percentage to the public; if that had been Dr. Tanaka's intent, he would not have included 11 grams of phospholipid among the added ingredients. See *id.* Equally (or more) plausible is the notion that Dr. Tanaka intended the added ingredients to bolster the neutral lipid content of the precursor, which (at 0.2%) was below the level claimed in the '839 patent.

Accordingly, the '839 patent never discloses or even hints that a composition with a phospholipid content of 92.8% might serve as an alternative to the claimed composition or that it could be used as a final product in the treatment of respiratory distress syndrome. Moreover, Example 3 of the patent does not describe any alteration of the claimed compositional ranges in order to preserve patentability. Given the true context of the cited reference in Example 3, there was obviously no surrender of equivalents, much less a "clear and unmistakable" surrender of the sort that can trigger estoppel. *KCJ Corp.* v. *Kinetic Concepts, Inc.*, 223 F.3d 1351, 1359 (Fed. Cir. 2000). Dey has cited no authority to support the view that the patentee of a particular chemical composition intentionally surrenders all precursor compounds and byproducts formed at intermediate stages merely by complying with the statutory requirement that mandates a complete description of how to "make and use" the invention. 35 U.S.C. § 112.

As this analysis shows, Example 3 of the '839 patent's specification does not "expressly disclaim" an alternative composition as Dey contends. For purposes of this petition, however, it is sufficient that the court below did not accept or even comment upon Dey's suggestion that an alternative composition was expressly disclosed and disclaimed. Without some discussion on this point, the opinion below does not conflict with any of the other decisions cited in Dey's petition.

### B. The Alleged Conflicts Between The Decision Below And Other Federal Circuit Decisions Are Illusory.

Given that the Federal Circuit did not adopt (or even mention) Dey's position on this factual issue, there is no conflict between the decision below and the Federal Circuit's opinions in *Johnson & Johnston Assocs. Inc.* v. *R.E. Service Co.*, 285 F.3d 1046 (2002) (en banc), *Maxwell* v. *J. Baker, Inc.*,

86 F.3d 1098 (1996), and *Sage Products, Inc.* v. *Devon Indus., Inc.*, 126 F.3d 1420 (1997).

The *Johnson* case related to the manufacture of printed circuit boards, which are composed of sheets of copper foil layered with sheets of a nonconducting material. 285 F.3d at 1048. The patent claimed an assembly to aid in the manufacture of the boards by adhering the very fragile sheets of copper foil to a more substantial "substrate" sheet of aluminum. When the copper foil was attached to the substrate, workers could more easily handle it and could assemble the boards with minimal risk of damaging the foil. *Id.* at 1049. The patent's specification described the function of the substrate as follows:

> The use of the adhered substrate * * *, regardless of what material it is made of, makes the consumer's (manufacturer's) objective of using thinner and thinner foils and ultimately automating the procedure more realistic since the foil, by use of the invention, is no longer without the much needed physical support.

*Id.* at 1049-1050 (quoting U.S. Patent No. 5,153,050) (emphasis added). Although the patent claimed a substrate made of aluminum only, the specification clearly stated that other materials could be used just as effectively:

> While aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys, may be used. In some instances * * * polypropelene [sic] can be used.

*Id.* at 1050 (quoting the '050 patent).

The critical feature of the patent in *Johnson* was that it expressly stated that an alternative composition would perform

in the same manner as the claimed composition. *Id.* ("'*other* metals * * * may be used'"); *id.* at 1049 (substrate would have the desired effect "'regardless of what material it is made of'"). The Federal Circuit relied on this statement in concluding that the patentee could not use the doctrine of equivalents to show that an assembly using a stainless steel substrate infringed the patent. *Id.* at 1055. Quoting the above description of the substrate's composition, the court explained that the patentee had "disclosed without claiming the steel substrates" and "cannot now invoke the doctrine of equivalents to extend its aluminum limitation to encompass steel." *Id.*

The Federal Circuit followed the same analysis in *Maxwell*, which preceded and was reinforced in *Johnson*. In *Maxwell*—which concerned a system for attaching pairs of shoes together—the patentee disclosed that an alternative system would have performed the same function: though the patentee "limited her claims to fastening tabs attached between the inner and outer soles" of the shoes, she disclosed "alternatives in which the fastening tabs could be 'stitched into the lining seam of the shoes.'" 86 F.3d at 1108. By failing to claim these "alternate shoe attachment systems," the patentee "dedicated the use of such systems to the public." *Id.*; cf. *SciMed Life Sys., Inc.* v. *Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir. 2001) (patentee could not invoke doctrine of equivalents when patent specifically identified and criticized the alternative device that allegedly infringed).

The basic factual predicate to Dey's arguments based on these cases is simply wrong—or at least unproven and never adopted by the courts below. Unlike in *Johnson* and *Maxwell*, the opinion below does not hold or suggest that the '839 patent expressly disclaims an alternative to the claimed composition.

Indeed, as discussed above, Example 3 of the '839 patent does not even hint that the precursor compound derived at a preliminary stage of the production process could actually be used in the treatment of a human infant. On the contrary, under Example 3, additional materials had to be added to the precursor product before it would become a final, useable product. The patent's specification properly set forth in detail both the composition of the precursor material and the manner in which the final composition was obtained. This kind of discussion is fundamentally different from the express disclosure of an *alternative* to the claimed composition, as found in *Johnson* and *Maxwell*. At a minimum, given the absence of any factual finding that the patent "expressly disclaim[s]" a compound with a higher level of phospholipid, there is no conflict between the decision below and the settled law of the Federal Circuit.

In arguing for rehearing before the Federal Circuit, Dey contended that *Johnson* and *Maxwell* cannot be limited to cases where the patent expressly discloses an "alternative" to the claimed invention, because that reading would represent a return to the principles set out in *YBM Magnex, Inc.* v. *International Trade Comm'n*, 145 F.3d 1317 (Fed. Cir. 1998), which *Johnson* expressly overruled. That is nonsensical. To say that a patent "discloses" and fails to claim a different composition necessarily means that the patent must disclose it *as an alternative* to the claimed invention.[4] The en banc court

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[4] In addition, to the extent that a subject matter disclosed but unclaimed by a patent is "dedicated" to the public under *Johnson*, a third party would be entitled to practice a similar invention only if it is exactly the same composition as the one disclosed and left unclaimed. Dey distorts this notion by suggesting that the '839 patent dedicates one individual *element*—a phospholipid level—in

in *Johnson* was critical of *YBM Magnex* for a different reason: it characterized *YBM Magnex* as incorrectly attempting to limit *Maxwell*'s preclusion on the doctrine of equivalents "to situations where a patent discloses an unclaimed alternative *distinct from the invention*." 285 F.3d at 1052 (emphasis added); see also *YBM Magnex*, 145 F.3d at 1320 (describing *Maxwell* as precluding reliance on the doctrine of equivalents because of "the distinctness of the two embodiments" described in the specification). Thus, the error in *YBM Magnex* stemmed from its conclusion that reliance on the doctrine of equivalents is precluded only where the disclosed alternative is markedly "distinct from" the claimed invention. By overruling *YBM Magnex* in *Johnson*, the Federal Circuit made clear that the doctrine of equivalents is unavailable whenever a patent expressly discloses and fails to claim an alternative to the claimed invention, whether "distinct" or not. Nothing in *Johnson* suggests that the doctrine of equivalents would be barred in the instant case, where the court below did not find or mention any express disclosure of an alternative to the claimed invention (and where, in fact, there was no such disclosure).

Further, the panel in this case was well aware of *Johnson* both during oral argument and at the time of its decision, even without briefing by the parties. *Johnson* was argued to the Federal Circuit en banc on October 3, 2001 and was decided less than one month before the decision here was rendered. The *Johnson* case was obviously an important case in the Federal Circuit, as it resolved an apparent tension between two previous

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isolation, apart from any other components of the composition. In fact, Dey's own composition is *not* the same in all respects as the precursor compound described in Example 3 of the '839 patent. It does not even have the same 92.8% level of phospholipid that is contained in the precursor compound. See *supra* at 1 n.1.

decisions by overruling one of them. Two of the three panel judges in this case (including the author of the panel opinion) joined the per curiam opinion for the court in *Johnson*. The third panel member (Judge Newman) dissented from the court's opinion in *Johnson* with an extensive written opinion. Clearly, when the panel issued its opinion here, all three members of the panel were well aware of how the en banc court had resolved the *Johnson* matter. Thus, it is not surprising that the panel's decision is entirely consistent with *Johnson*.[5]

Dey also claims that the decision below is in conflict with *Sage Products, Inc.* v. *Devon Industries, Inc.*, 126 F.3d 1420 (Fed. Cir. 1997). Dey characterizes that case as holding that the doctrine of equivalents is unavailable for any subject matter that would have been foreseeable at the time of filing and could have been claimed in the patent by one skilled in the art. Even accepting that characterization, there is no conflict with the decision below. At this stage in the proceedings, there has been no factual finding that a skilled patent drafter would have foreseen that a composition with a higher level of phospholipid could have been used effectively in the treatment of human infants. To the extent that Dey is basing its "foreseeability" argument on the patent's supposed "express disclaimer" of higher phospholipid levels in Example 3, that proposition is at best unproven and at worst flatly wrong. Thus, there is no real conflict with *Sage Products*.

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[5] Furthermore, in its petition for rehearing and suggestion for rehearing en banc, Dey fully briefed the *Johnson* case and gave both the panel and the full Federal Circuit the opportunity to address any possible conflict between that case and the decision below. Dey's rehearing petition was denied, and the full court declined the suggestion to rehear the case en banc.

### C. Dey Has Not Identified Any Inconsistency Between The Decision Below And Previous Decisions Of This Court.

Dey also seeks certiorari on the ground that the Federal Circuit's decision "disrupts the expectations" created by this Court's most recent decisions on the doctrine of equivalents: *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002), and *Warner-Jenkinson Co.* v. *Hilton-Davis Chemical Co.*, 520 U.S. 17 (1997). Pet. 19; see also *id.* at 22-24. Dey even argues that the decision below should be remanded for further consideration in light of *Festo*, which was handed down after the Federal Circuit's decision in this case. Pet. 11. Once again, however, these arguments rely heavily on Dey's factual supposition that in this case the alleged equivalent "was foreseeable, disclosed and surrendered" by the '839 patent. Pet. 21; see also *id.* at 22 (asserting that the '839 patent disclosed and failed to claim a higher range of phospholipids and citing Example 3); *id.* at 24 (arguing that claim construction "will have no meaning" if the doctrine of equivalents can be used "to encompass subject matter that a patent holder expressly disclosed and surrendered").[6] As explained above, the factual predicate to these arguments was

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[6] In this context, Dey also relies on the prosecution history of the '301 patent, arguing that the patent holder retreated from the prior art by arguing the importance of the specific percentage ranges described in that patent's claims. Pet. 21. As the Federal Circuit properly held, however, "the relationship, if any, between the '839 and '301 patents is insufficient to render particular arguments made during prosecution of the '301 patent equally applicable to the claims of the '839 patent." Pet. App. 13a.

never adopted by the courts below and is strenuously disputed by plaintiffs.[7]

As for *Festo*, the petition does not attempt to identify any specific conflict or tension with the opinion below but merely attributes to *Festo* the view that the doctrine of equivalents should not be used too broadly. Pet. 19-24.[8] Dey also describes a parade of horribles that it concludes will follow from the decision below. *Id.* at 24. If the '839 patent did *not* "expressly disclose and surrender" the relevant subject matter, however, then even Dey would have to concede that there is no parade of horribles. Given the continuing dispute over that factual proposition and the complete absence of a finding by the court below that the patent expressly disclosed the relevant subject matter, Dey's argument loses any force it might conceivably have.

Dey also suggests that the decision below conflicts with *Warner-Jenkinson*'s warning that the doctrine of equivalents should not be used to eliminate an element in its entirety. Pet.

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[7] Dey may argue that the Federal Circuit's failure to address Example 3 and the alleged "express disclaim[er]" is itself error that requires correction. In plaintiffs' view, however, the absence of this argument from the published opinion simply reflects the argument's obvious lack of merit and the fact that it was offered as (at most) a side-light to Dey's principal argument on appeal—namely, that the prosecution history of the '301 patent and the relationship between the two patents precluded application of the doctrine of equivalents. In any event, this sort of error would not be worthy of a grant of certiorari.

[8] Dey ignores the fact that *Festo* significantly *expanded* the availability of the doctrine of equivalents in cases of prosecution history estoppel. *Festo*, 122 S. Ct., at 1840-1842.

20 (citing 520 U.S. at 28-29). Under the facts of this case, however, there is no such conflict. The Federal Circuit specifically held, based upon the evidentiary record in this case, that plaintiffs' expert testimony and their reliance on the doctrine of equivalents did *not* vitiate the upper limit on phospholipids. Pet. App. 20a (although the expert testimony regarding the equivalence of the different levels of phospholipid effectively "expands the upper limit beyond the range literally recited by the claim, it does not eliminate the upper limit altogether"). Thus, there is no conflict between the decision below and *Warner-Jenkinson*.

## II. The Alleged Conflict Between Two Federal Circuit Decisions Relating To The Patents At Bar Is Illusory And Does Not Merit This Court's Attention.

Dey's petition also asks this Court to resolve an alleged conflict between the decision below and the Federal Circuit's opinion in *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305 (2001), which also concerned the '301 and '839 patents. Pet. 16-17. According to Dey, the two decisions are in disagreement about whether statements made during the file history of the '301 patent can create prosecution history estoppel for the '839 patent. *Id.*

Dey's argument misstates the holding in *Forest Laboratories* and overstates the significance of the issue of prosecution history estoppel in that case. In *Forest Laboratories*, the Federal Circuit considered whether the district court had erroneously granted judgment of noninfringement of the '301 and '839 patents following a jury verdict to the contrary. The court affirmed the district court's decision on the ground that Abbott had failed to present any evidence that the accused products met the water limitation contained in both claims either literally or under the doctrine of

equivalents. 239 F.3d at 1312-1313. The court added that an argument made during the prosecution of the '301 patent (namely, that "only a surface-active material having the chemical composition claimed and disclosed" in the '301 application would have the desired therapeutic effect) led to the conclusion that plaintiffs were estopped from asserting that the percentage of water was irrelevant. *Id.* at 1314.

Significantly, however, the court in *Forest Laboratories* did not mention prosecution history estoppel with respect to the '839 patent specifically. The opinion's brief discussion of estoppel (which was *dicta* in any event) cited only the prosecution history of the '301 patent and thus provided an alternative ground for affirmance for that patent only. Dey's current reading of *Forest Laboratories* is strained indeed; given that Dey could cite no authority for the proposition that one patent's history can work an estoppel in an unrelated patent, it is extremely unlikely that the Federal Circuit would have adopted that novel argument and dramatically expanded the doctrine of prosecution history estoppel without explicitly stating that it was doing so.

In any case, because *Forest Laboratories* does not expressly discuss why or even whether it would have used the '301 patent's history as estoppel with respect to the '839 patent, any conflict with the decision here is illusory. The decision below carefully explains that under the facts of this case, any statements made in the prosecution of the '301 patent did not and could not limit the use of the doctrine of equivalents to show infringement of the '839 patent. Pet. 11a-15a. With no explicit holding or reasoning to the contrary, *Forest Laboratories* hardly constitutes conflicting precedent justifying a grant of certiorari.

Finally, even if Dey's reading of *Forest Laboratories* were correct, the relationship between the '301 and '839 patents is of very limited concern. As noted above, the Federal Circuit's analysis of the issue in this case turned on the specific facts and circumstances underlying these particular patents. Any lingering dispute about the relationship between these specific patents would not be worthy of this Court's attention.

## CONCLUSION

The petition for certiorari should be denied.

Respectfully submitted.

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